



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0261]

Food and Drug Administration

The Meaning of “Spouse” and “Family” in the Food and Drug Administration’s Regulations after the Supreme Court’s Ruling in United States v. Windsor--Questions and Answers:

Guidance for Industry, Consumers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled “The Meaning of ‘Spouse’ and ‘Family’ in FDA’s Regulations after the Supreme Court’s Ruling in United States v. Windsor--Questions and Answers: Guidance for Industry, Consumers, and FDA Staff.” This guidance informs the public of FDA’s interpretation of the effects of the Supreme Court’s decision in United States v. Windsor on several of its regulations. This guidance has an immediate implementation date because FDA has determined that prior public participation is not feasible or appropriate.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel W. Sigelman, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD 20993, 301-796-4706, email: daniel.sigelman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled, “The Meaning of ‘Spouse’ and ‘Family’ in FDA’s Regulations after the Supreme Court’s Ruling in United States v. Windsor--Questions and Answers, Guidance for Industry, Consumers, and FDA Staff” dated March 2014.

On June 26, 2013, in United States v. Windsor, 133 S.Ct. 2675, the U.S. Supreme Court struck down as unconstitutional section 3 of the Defense of Marriage Act (Pub. L. 104–199). In the guidance we set forth how we will interpret the terms “spouse” and “family” in our regulations in accordance with this decision.

Because this guidance provides FDA’s interpretation of these terms in light of a ruling of the Supreme Court, this guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency’s Good Guidance Practices regulation.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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